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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,420	04/16/2004	Kyungyoon Min	F-6097 (0360-0146)	9851

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EXAMINER	
ZALUKAEVA, TATYANA	

ART UNIT	PAPER NUMBER
3761	

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/826,420	MIN ET AL.	
	Examiner	Art Unit	
	Patricia M. Bianco	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/26/04;12/8/04;6/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Detailed Action*.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the step of the blood being "**processed sequentially**" in claim 11, the step of the blood being "**processed simultaneously**" in claim 12, and the step of "**pooling together blood from other blood sources and flowing the pooled blood into the flow path for processing**" in claim 13 are not recited in the specification.

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because it contains legal phraseology. Correction is required. See MPEP § 608.01(b).

The use of the trademarks has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology. It appears that numerous trademarks have been recited without proper indication (such as ® or ™) after each. Clarification and proper indication of trademarks is required for the following: AMICUS®, AYLX®, AUTOPHERESIS-C®, THE SPECTRA® and TRIMA® throughout the specification (pgs. 4, 5, 10, & 11).

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 9 recite the limitation "**the reusable device**" in line one of the claims. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7, 10-13, and 15-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Wahl et al. (5,653,887). Wahl et al. (hereafter Wahl) discloses an apheresis blood processing apparatus and method for processing whole blood into its separated components. Wahl discloses a disposable set (8) and a blood separation device (6) that includes a processing centrifuge assembly (i.e. blood processing chamber). The disposable set also includes various tubing and a plurality of collection containers 84/94 (see figures 1 and 2). The collection containers have a volume that is capable of holding a unit of blood or a volume between 200 ml and 750ml. Wahl further teaches that an anticoagulant source is added to the container that holds whole blood.

Wahl teaches of a method for collecting and separating whole blood that includes the steps of providing a disposable blood separation circuit that is adapted to cooperate with a reusable separation controller (200 & 1000 on figure 1) and connecting a patient (i.e. blood source) to the disposable for collecting whole blood into a collection container. However, the recitation that the disposable is "adapted to cooperate with a reusable separation controller" has not been considered sine it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138. Wahl further teaches that the patient or blood source may be disconnected from the disposable by means of sealing the line (col. 55, lines 60-67 & col. 59, lines 1-5). To commence the blood separation process, the disposable is connected to the blood processing chamber (200) (i.e. is mounted to the chamber) that is associated with the controller. With respect to claim

10, Wahl refers to a patient/donor as providing the whole blood; the patient/donor is inherently seen to be a human.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wahl et al. (5,653,887). Wahl et al. (hereafter Wahl) discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the reusable device is not in the immediate vicinity of the source during collecting, or is at a different location than where collection takes place. However, at the time of the

invention, it would have been an obvious matter of design choice to perform the step of collecting away from the reusable device as to save space in a collection facility and make the patients more comfortable, since applicant has not disclosed that the separation of the reusable device and the source during collection solves any stated problem or is for any particular purpose and it appears that the invention would perform equally well with the device and method of Wahl. Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be clearly disclosed in the specification or supplied by affidavit. See In re Cole, 140 USPQ 230 (CCPA 1964).

Claims 4-6, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wahl et al. (5,653,887) in view of Robinson et al. (6,695,803). Wahl et al. (hereafter Wahl) discloses the invention substantially as claimed, see rejection supra, however, fails to disclose specifically that the method require the initial collection of whole blood to be any of the following volumes: about 200-750 ml; about 500 ml; a unit; or about 405-550 ml.

Robinson et al. (hereafter Robinson) teaches a method of processing whole blood from a patient and that the whole blood is separated into components. Further, Robinson teaches that the system allows for collecting two units of blood. (Col. 23, lines 13-22). It is well known in the art that one unit of blood may be equivalent to one pint, or approximately 473 ml, or in the range of 250 cc to 450 cc. Since Wahl teaches of a method for separating whole blood wherein the amount of whole blood collected

from a patient may be based on the time a patient/donor has to donate and the patient/donor's blood volume, it would have been obvious to modify the amount of blood collected to collect up to two pints of blood from the patient as taught by Robinson as a matter of obvious design choice, since applicant has not disclosed that the volume or unit of blood is critical to the method. Applicant is also reminded that arguments toward the criticality of an element will generally be given little patentable weight. The basis for criticality should be clearly disclosed in the specification or supplied by affidavit. See In re Cole, 140 USPQ 230 (CCPA 1964). Further, Applicant appears to show that the collection volume is not critical in the statement in the specification that the amount of blood collected may be such an amount "as the user desires" or is "consistent with the health of the donor" and further states that a typical "unit" of whole blood "may be defined by the particular collecting agency or as defined by any applicable regulatory body, rule or guideline" (see page 3, paragraph [00010] of the specification).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Schoendorfer (4,402,680), Lysaght et al. (4,964,976), Tanokura et al. (5,523,004), Headley et al. (6,632,191), and Hlavinka et al. (7,033,512) all disclose analogous methods and systems for separating whole blood into components.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia M. Bianco whose telephone number is (571)

272-4940. The examiner can normally be reached on Monday to Friday 9:00-6:30, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 30th, 2006

Patricia M Bianco
Primary Examiner
Art Unit 3761

PATRICIA BIANCO
PRIMARY EXAMINER